

**UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF NEW JERSEY  
CAMDEN VICINAGE**

**IN RE: VALSARTAN, LOSARTAN,  
AND IRBESARTAN PRODUCTS  
LIABILITY LITIGATION**

MDL No. 2875

Honorable Robert B. Kugler,  
District Court Judge

Honorable Thomas Vanaskie  
(Ret.),  
Special Discovery Master

**[PROPOSED] ORDER  
GRANTING MOTION TO  
SEAL PURSUANT TO  
L.CIV.R. 5.3(g)**

THIS MATTER having been brought before the Court by way of the Motion to Seal the transcript of the Court's hearing dated September 10, 2021 (the "Sept. 10 Transcript") pursuant to Local Civil Rule 5.3(g) (the "Motion to Seal") filed by Defendants Zhejiang Huahai Pharmaceutical Co., Ltd. ("ZHP"), Princeton Pharmaceutical Inc. ("Princeton"), Huahai U.S. Inc. ("Huahai U.S."), and Solco Healthcare U.S., LLC ("Solco," and collectively with ZHP and Princeton, "the ZHP Parties") on notice to liaison counsel for Plaintiffs; and the Court having considered the parties' submissions and proposed information requested to be sealed, and the criteria contained in Local Civil Rule 5.3(g), and, by reference, Local Civil Rule 5.3(c)(2); and the Court having further found that the standards set forth in Local

Rule 5.3(c)(2) and (g) have been met, the Court makes the following Findings of Fact and Conclusions of Law:

### **FINDINGS OF FACT**

1. Through discovery in this case, the ZHP Parties have produced confidential information, the public disclosure of which would affect ZHP's legitimate business interests and competitive standing. To protect the confidentiality of information produced in discovery in this case, the parties negotiated and agreed to maintain the confidentiality of any materials produced pursuant to the Confidentiality and Protective Order (the "Protective Order"), entered by the Honorable Robert B. Kugler on June 26, 2019 (Dkt. No. [139](#)).

2. The Protective Order permits the producing party to safeguard information by designating a document either "CONFIDENTIAL INFORMATION" or "RESTRICTED CONFIDENTIAL INFORMATION."

3. The Protective Order defines the type of information that warrants a confidentiality designation:

The term "CONFIDENTIAL INFORMATION" as used in this Protective Order means all information produced by any party in the course of discovery or other proceedings in this case (electronic or otherwise) which is proprietary, trade secret and/or highly sensitive commercial information, and which is believed in good faith by the Producing Party to have the potential, if disclosed, for causing competitive harm to it or giving a competitive advantage to others, and/or which is not publicly available and which a party believes in good faith

to be subject to federal, state, or foreign data protection laws or other similar privacy obligations imposed by law.

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“RESTRICTED CONFIDENTIAL INFORMATION” means Documents that a Party has designated as “RESTRICTED CONFIDENTIAL” in accordance with this Protective Order and includes Documents a Party reasonably believes contain, describe, identify, or refer to highly confidential commercial, business, financial, or competitive information including **proprietary manufacturing and production information (including formulation)**; business and prospective marketing plans; trade secrets; customer lists; pricing, market share, product cost and projected sales data; data relating to mergers and acquisitions; other information of a highly sensitive nature about the Party, which is not publicly available, the disclosure of which could cause the Producing Party competitive harm . . .

(Dkt. No. [139](#), ¶¶ 9(B), (M)) (emphasis added).

4. The Protective Order also takes a pragmatic view of confidentiality designations given the size and scope of this litigation.

It is anticipated that the volume of documents to be exchanged by the parties during pre-trial discovery may be substantial. Accordingly, nothing herein shall be construed to prevent a Producing Party from designating documents as “CONFIDENTIAL INFORMATION” in order to expedite the flow of discovery and to facilitate discovery in these consolidated actions . . . .

(*Id.* at ¶ 9(B)).

5. This is particularly true where, as here, the ZHP Parties are competitors not only with the other manufacturer defendants in this MDL, but also with

companies not included in this MDL, in the highly competitive generic drug marketplace. The Protective Order is designed to ensure that documents properly designated as either “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION” are not subject to unfettered disclosure to protect the parties from the risk of significant competitive harm.

6. Pursuant to the Protective Order, a party may designate a document as “CONFIDENTIAL INFORMATION” or “RESTRICTED CONFIDENTIAL INFORMATION,” and, if so, the information may only be used for purposes of this litigation and may only be disclosed to designated persons. *Id.* at ¶¶ 22, 24.

7. The Protective Order further provides that “All portions of any ... hearing transcript taken in the Litigation, wherein the Documents themselves, or the contents of the Documents, designated as PROTECTED INFORMATION are identified, discussed, or disclosed, shall also be designated as PROTECTED INFORMATION and shall be subject to the terms of this Protective Order.” *Id.* at ¶ 17(B).

8. Under Paragraph 17(B) of the Protective Order, the ZHP Parties have thirty (30) days following the receipt of a transcript to designate such portions that are confidential, and provide notice of same to all parties. Until expiration of the thirty-day period, “the entire transcript will be treated as RESTRICTED

CONFIDENTIAL INFORMATION subject to protection against disclosure under this Protective Order.” *See id.*

9. On September 13, 2021, the ZHP Parties received the Sept. 10 Transcript of the hearing before Special Discovery Master Judge Vanaskie on Plaintiffs’ Motion to Compel (Dkt. No. [1405](#)). *See* Bonner Decl. at ¶ 3.

10. This hearing was conducted *in camera* at the request of the parties so that they could freely discuss documents that had been previously designated as “RESTRICTED CONFIDENTIAL INFORMATION” by the ZHP Parties. *See id.* at ¶ 4. Consequently, the Sept. 10 Transcript was temporarily sealed pending an Order by this Court. *See id.* at ¶ 4.

11. Because the Sept. 10 Transcript identifies, discusses, and discloses documents designated as “RESTRICTED CONFIDENTIAL INFORMATION” pursuant to Paragraph 9(M) of the Protective Order, the ZHP Parties formally move to redact and seal portions of the Sept. 10 Transcript pursuant to Paragraph 17(B) of the Protective Order, as well as Local Civil Rule 5.3(g).

12. The ZHP Parties seek to redact and seal only those portions of the Sept. 10 Transcript that contain discussion of documents designated by the ZHP Parties as “RESTRICTED CONFIDENTIAL INFORMATION” pursuant to the Protective Order.

13. These documents consist of: (1) an internal email dated July 27, 2017 from a ZHP employee, Jinsheng Lin of ZHP's technical analysis department (CEMAT), regarding ZHP's efforts to optimize its processes for manufacturing irbesartan. The Lin email was marked by Plaintiffs as Exhibit ZHP 295 (the "July 27, 2017 email") and ZHP 296 (its English translation); and (2) excerpts of the deposition testimony of Dr. Min Li dated April 20, 2021, in which Dr. Li was asked to disclose his knowledge of the July 27, 2017 email. Both the July 27, 2017 email and the relevant portions of Dr. Li's testimony addressing the July 27, 2017 email were designated "RESTRICTED CONFIDENTIAL INFORMATION" by the ZHP Parties.<sup>1</sup>

14. The July 27, 2017 email, which was internal to ZHP and not intended for external dissemination, was prepared by Jinsheng Lin as part of a project by ZHP to improve its manufacturing processes for irbesartan API—not valsartan—at the research and development stage. *See* Dr. Li Decl. at ¶¶ 3-5.

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<sup>1</sup> The July 27, 2017 email (ZHP00190573-74) is presently one of the documents subject to Plaintiffs' motion that the ZHP Parties waived their confidentiality designations (Dkt. No. [1392](#)). This motion is fully briefed and *sub judice*. The ZHP Parties have denied Plaintiffs' waiver allegations with respect to the July 27, 2017 email, and maintain that this document is "RESTRICTED CONFIDENTIAL INFORMATION." *See generally* The ZHP Parties' Memorandum of Law in Opposition to Plaintiffs' Contentions that the ZHP Parties Waived Certain Confidentiality Designations (Dkt. No. [1404](#) at 5-9).

15. The information disclosed in the July 27, 2017 email is highly confidential, proprietary, and competitively sensitive, and was properly designated as “RESTRICTED CONFIDENTIAL” under the Protective Order. *See id.* at ¶ 6.

16. The ZHP Parties believe in good faith that if the contents of the July 27, 2017 email were disclosed through counsels’ discussions in the Sept. 10 Transcript, they will suffer significant competitive harm in the form of disclosure of their proprietary API process optimization efforts and related testing to their direct competitors, and that such disclosure would impede and impair the ability of ZHP to compete in the highly competitive pharmaceutical API and finished dose product market. *See id.* at ¶¶ 8-10.

17. Courts have recognized that the presumption of public access is not absolute and may be rebutted. *See In re Avandia Mktg., Sales Practices & Prods. Liability Litig.*, 924 F.3d 662, 672 (3d Cir. 2019). The party seeking to overcome the presumption of access must show “that the interest in secrecy outweighs the presumption.” *Avandia*, 924 F.3d at 672 (3d Cir. 2019) (quoting *Bank of Am. Nat’l Tr. & Sav. Ass’n v. Hotel Rittenhouse Assocs.*, 800 F.2d 339, 344 (3d Cir. 1986)). To do so, the movant must demonstrate “that the material is the kind of information that courts will protect and that disclosure will work a clearly defined and serious injury to the party seeking closure.” *Id.* (quoting *Miller v. Ind. Hosp.*, 16 F.3d 549, 551 (3d Cir. 1994)); *Publicker Indus., Inc. v. Cohen*, 733 F.2d 1059, 1071 (3d Cir.

1984)); *Pansy*, 23 F.3d at 787. The Court must then determine if the harm from the articulated injury outweighs the presumption of access. *Pa. Nat'l Mut. Casualty Ins. Grp. v. New Eng. Reins. Corp.*, 840 F. App'x 688, 690 (3d Cir. 2020).

18. Under Local Rule 5.3(c) governing the standards that a motion to redact and seal a transcript must satisfy pursuant to Local Rule 5.3(g)(4), documents may be filed and maintained under seal upon a showing of good cause. *See* D.N.J. L. Civ. R. 5.3(c); *Vista India, Inc. v. Raaga, LLC*, No. 07-cv-1262, 2008 WL 834399, at \*3 (D.N.J. Mar. 27, 2008). The moving party must show that the following factors weigh in favor of sealing the information at issue: (1) the nature of the materials or proceedings at issue; (2) the legitimate private or public interest which warrants the relief sought; (3) the clearly defined and serious injury that would result if the relief sought is not granted; and (4) why a less restrictive alternative to the relief sought is not available. *See* D.N.J. L. Civ. R. 5.3(c)(3). This Court has discretion in balancing the factors for and against access to court documents. *See Pansy v. Stroudsburg*, 23 F. 3d 772, 791 (3d Cir. 1994).

19. As set forth below, the ZHP Parties satisfy the criteria for sealing set forth in Local Rule 5.3(c).



**A. The ZHP Parties' Legitimate Interest in Maintaining the Confidentiality of Portions of the Sept. 10 Transcript**

20. The ZHP Parties have a legitimate interest in maintaining the confidentiality of its proprietary research and development, manufacturing and production information, including its proprietary testing processes and API optimization efforts pursuant to Paragraph 9(M) of the Protective Order.

21. This Court, and courts construing New Jersey law, have repeatedly recognized the need to protect from disclosure confidential research, development, product testing, and other trade secret information involving pharmaceutical manufacturers to protect a litigant's standing in the marketplace. *See, e.g., Impax Labs., Inc. v. Zydus Pham. (USA) Inc.*, 2:17-cv-13476, 2018 WL 6416910, at \*3 (D.N.J. Dec. 6, 2018) (stating, "this Court has protected confidential research and development, product testing, formulations, and other trade secret information, including, but not limited to, the confidential nature of ANDAs, drug master files, formulations, and other confidential testing by drug manufacturers"); *In re Gabapentin Patent Litig.*, 312 F. Supp. 2d at 667 (affirming magistrate judge's denial of motion to unseal documents that contained information relating to defendant's ANDA, DMF, processes, formulations, and testing); *Valeant Pharm. Luxembourg S.à r.l. v. Actavis Labs. UT, Inc.*, No. 2:16-cv-4344, 2018 WL 1469050, at \*3 (D.N.J. March 26, 2016) (same); *Boehringer Ingelheim Pharma GmbH & Co. KG v. Mylan Pharm. Inc.*, No. 1:14-cv-4727, 2015 WL 4715307, at \*2 (D.N.J. Aug.

7, 2015) (sealing documents that producing party designated highly confidential because they “contain or reflect ... highly proprietary business information regarding the development, formulation, manufacture and sales of ANDA products”); *Depomed, Inc. v. Purdue Pharma L.P.*, No. 13-571, 2017 U.S. Dist. Lexis 212, at \*6-8 (D.N.J. Jan. 3, 2017) (sealing confidential manufacturing and research and development processes and information as well as internal documents, such as laboratory notebooks).

22. Similarly, this Court has recognized the need to protect from disclosure internal communications and discussions regarding ZHP’s API process optimization efforts where ZHP has “sufficiently rebutted the presumption of public access by making a specific showing of competitive harm.” *See In re: Valsartan, Losartan and Irbesartan Prods. Liab. Litig.*, MDL No. 2875, dated May 24, 2021 at 18-19 (the “May 24, 2021 Order”) (granting motion to seal internal notes regarding ZHP’s process optimization strategies where disclosure “would result in significant competitive harm by allowing [competitors] to benefit from ZHP’s proprietary research and development while the FDA restricts ZHP from exporting its products into the U.S. market.”).

23. The July 27, 2017 email contains commercially sensitive, non-public, information regarding ZHP’s proprietary process optimization efforts and related testing as to irbesartan API, a different product than valsartan. *See Dr. Li Decl.* at ¶

6. It represents the concerted time, efforts, and expenditures by ZHP, and in particular, CEMAT and the Technology Department of its Chuannan facility, to test and improve the process by which it manufactured irbesartan API at the research and development stage. *See id.* at ¶¶ 4-5.

24. Specifically, the July 27, 2017 email focuses on (1) proprietary technical improvements that were tested by the Chuannan facility's Technical Department regarding irbesartan, (2) the Technical Department's communications with CEMAT regarding certain technical changes observed during the attempted process improvements, and (3) CEMAT's subsequent analysis of these changes. *See Dr. Li Decl.* at ¶ 6. The July 27, 2017 email also proposes additional testing by CEMAT to simulate the processes attempted by the Technical Department and resulting conditions, and to monitor and verify the results. *See id.* at ¶ 7.

25. Thus, the disclosure of the July 27, 2017 email would be of significant competitive value to ZHP's many competitors in the generic drug marketplace, including, but not limited to, those named as defendants in this MDL. Moreover, this Court has held this type of information to be properly confidential. *See* May 24, 2021 Order at 18-19; *see also Novartis Pharms. Corp. v. Mylan Pharms., Inc.*, No. 06-2885 (MLC), 2008 WL 11383884 at \*1-2 (D.N.J. Oct. 31, 2008) (granting motion to seal documents, including confidential communications with the FDA, where Novartis had a legitimate business interest in preventing the disclosure of

confidential and proprietary information, and where disclosure of such information would result in competitors gaining an unfair competitive advantage in the marketplace).

**B. If the Portions of the Sept. 10 Transcript Whose Redaction is Sought Were Disclosed, ZHP Would Suffer a Clearly Defined and Serious Injury**

26. The clearly defined and serious injury that would result should the proposed Order to seal not be entered is that the ZHP Parties would suffer significant competitive harm as a result of the disclosure to their competitors of their proprietary API process optimization strategies, testing and procedures relative to irbesartan, a widely prescribed and used antihypertensive medication.

27. It is well-known that the pharmaceutical industry is a “highly competitive market where companies routinely attempt to discover a possible advantage over their competitors.” *See Public Citizen Health Research Grp. v. NIH*, 209 F. Supp. 2d 37, 47 (D.D.C. 2002); *see also United States ex rel. Brown v. Celgene Corp.*, No. CV 10-3165 GHK (SS), 2016 WL 6542729, at \*4 (C.D. Cal. Mar. 14, 2016) (“In a field as competitive and technical as the pharmaceutical industry, success or failure will turn in large measure on innovation . . . .”) (internal citation omitted).

28. As the Court is aware, many of the ZHP Parties’ direct competitors are defendants in this MDL, while other competitors who are not could readily access

this information if it were made publicly available. The disclosure of ZHP's proprietary irbesartan API optimization efforts would result in significant competitive harm to the ZHP Parties by allowing the ZHP Parties' direct competitors to implement and benefit from ZHP's research and development, and testing directed to optimizing irbesartan's manufacturing processes while the FDA restricts ZHP from exporting its products into the U.S. market, awarding a significant competitive advantage to the ZHP Parties' competitors. *See* Dr. Li Decl. at ¶¶ 8-10. Furthermore, such disclosure may well impede the ZHP Parties' ability to re-enter the U.S. market following the removal of the import ban. *See id.*

**C. There Is No Less Restrictive Alternative Available to Redacting and Sealing Portions of the Sept. 10 Transcript**

29. There is no less restrictive alternative available other than to redact and seal portions of the Sept. 10 Transcript referencing the July 27, 2017 email and the related deposition testimony of Dr. Min Li referencing this email. *See* Bonner Decl. at ¶ 9. The ZHP Parties have carefully analyzed the Sept. 10 Transcript to identify which information should be sealed, and have sought to redact only those portions of the Sept. 10 Transcript – approximately four pages in total – that disclose or reference the contents of the July 27, 2017 email, which the ZHP Parties previously designated as “RESTRICTED CONFIDENTIAL.” *See id.*

**D. There Is No Prior Order Sealing the Sept. 10 Transcript**

30. The Court’s hearing on Plaintiffs’ Motion to Compel was conducted *in camera* at the request of the parties to enable the parties to freely discuss documents and other matters at issue in that hearing.<sup>2</sup> *See* Bonner Decl. at ¶ 4. Likewise, the Sept. 10 Transcript was filed under seal to allow the parties time to review the transcript and propose redactions. *See id.* There is no prior Order sealing the Sept. 10 Transcript, or the confidential information discussed therein. *See* Bonner Decl. at ¶ 10.

**E. Plaintiffs’ Objections to Sealing the Sept. 10 Transcript**

31. Plaintiffs have objected to the sealing request on the grounds that confidential treatment is not justified under the Protective Order in light of their belief that the ZHP Parties have waived confidentiality as to the July 27, 2017 email and what they argue is a public health interest in this document. *See* Bonner Decl. at ¶ 11; *see also Avandia*, 924 F.3d at 671 (identifying “various factors that courts may consider when determining whether good cause exists and, by extension, whether a

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<sup>2</sup> Plaintiffs have acknowledged that their oral argument in support of their Motion to Compel could include information designated as confidential pursuant to the protective order. *See* Plaintiffs’ Letter to the Court dated August 24, 2021 (Dkt. No. [1498](#) at 7) (“Plaintiffs’ Motion to Compel ZHP’s Supplemental Production (Oral Argument Could Potentially Include Confidential Information)”); *see also* 8-25-21 Hrg. Tr. at 11:8-10 (THE COURT: “But if it’s covered by the confidentiality order, then it will be conducted *in camera*. All right?” ADAM SLATER: “Yes, Your Honor.”).

protective order should issue,” including, “whether confidentiality is being sought over information important to public health and safety.”). For several reasons, Plaintiffs’ contentions are incorrect and insufficient to de-designate the July 27, 2017 email and related deposition testimony.

32. First, as stated above, *supra* note 1, the ZHP Parties dispute Plaintiffs’ allegation that they waived confidentiality as to the July 27, 2017 email, and this issue has been fully briefed and is *sub judice*. See Bonner Decl. at ¶ 12. The ZHP Parties maintain the appropriateness of their confidentiality designation of the July 27, 2017 email, and their right to designate any transcripts discussing, identifying, or disclosing its contents as “RESTRICTED CONFIDENTIAL INFORMATION” pursuant to Paragraph 17(B) of the Protective Order.

33. Second, Plaintiffs have repeatedly asserted a nonspecific public health interest in seeking to defeat the ZHP Parties’ designation of documents as confidential under this Court’s Protective Order. See Bonner Decl. at ¶ 11. Such is the case here as well. However, the ZHP Parties’ interest in preserving the confidential and proprietary nature of internal communications, not intended for public dissemination, relating to improving and optimizing manufacturing processes of one of their pharmaceutical APIs, in this instance, irbesartan API, outweighs any public interest in disclosing such information. See Bonner Decl. at ¶ 13. In *Avandia*, the Court held that these factors were discretionary, not mandatory, and should be

considered as part of a balancing test. *See Avandia*, 924 F.3d at 671. Nor have Plaintiffs articulated how the disclosure of this information either safeguards public health or advances any current or immediate public health interest. *See Bonner Decl.* at ¶ 13.

34. Conversely, as outlined below, several of the *Avandia* factors weigh against disclosure of the Sept. 10 Transcript:

- Disclosure of information contained in the underlying emails to the ZHP Parties' direct competitors, including defendants in this MDL, would not promote fairness and efficacy—rather, it would risk and may result in competitive harm to the ZHP Parties from the disclosure of information of a proprietary and confidential nature never intended to be shared with others outside of the ZHP-affiliated companies;
- Jinsheng Lin is a ZHP employee whose internal communications solely to others at his company were not intended for public disclosure.

*See* Order Granting in Part and Denying in Part Motion to Seal dated May 24, 2021 (Vanaskie, J.) (Dkt. No. 1269) (citing *Avandia*, 924 F.3d at 670).

35. The Court, having considered this matter pursuant to Local Civil Rule 5.3(c), and the submissions in support of the Motion to Seal, finds that the ZHP Parties have satisfied their burden of establishing under Local Civil Rule 5.3(c) and (g) and applicable case law that the Sept. 10 Transcript ought to be redacted and sealed by the ZHP Parties because it describes documents designated as “RESTRICTED CONFIDENTIAL INFORMATION” under the Protective Order.



36. Pursuant to the foregoing Findings of Fact and Conclusions of Law,  
and for good cause shown:

**IT IS** on this \_\_\_\_\_ day of \_\_\_\_\_, 2021, hereby

**ORDERED** that the ZHP Parties' Motion to Seal is hereby **GRANTED**; and

**IT IS FURTHER ORDERED** that those portions of the Sept. 10 Transcript  
referencing documents designated as "RESTRICTED CONFIDENTIAL  
INFORMATION" shall be redacted and remain sealed.

**IT IS FURTHER ORDERED** that a copy of this Order shall be served on  
all counsel of record within \_\_\_\_\_ days of Plaintiffs' liaison counsel's receipt of this  
Order.

**Dated:** \_\_\_\_\_

By the Court:

\_\_\_\_\_  
Hon. Thomas Vanaskie, (Ret.)  
Special Discovery Master